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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/691,053 10/19/00 AGUR

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EXAMINER

LIN, J

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|-------------------------------|----------------------------|--|
| Office Action Summary | Application No. 09/691,053 | Applicant(s) AGUR et al | |
| | Examiner Jerry Lin | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-509 is/are pending in the application.
- 4a) Of the above claim(s) 66-233 and 332-465 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-65,234-331 and 466-509 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☒ Claims 1-509 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-65, 234-331, 466-509 in Paper No. 5 is acknowledged. There is an apparent typo in the applicant's election in Paper No. 4. Applicant listed claims 1 - 65, 234 - 441, and 466-509 to be included in Group I. However, Group I only includes claims 1-65, 234-331, and 466-509. To expedient prosecution, the examiner will only consider claims 1-65, 234-331, and 466-509.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not identify the citizenship of each inventor.

The declaration lists the citizenship of each inventor as "Israeli." "Israeli" is not a country.

Claim Objections

3. Claim 5 objected to because of the following informalities: "Thrompocyte" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 246 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This instant claim depends on a non-elected claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claim 1, 18, 23-26, 41, 46-49, 274, 296, 506 and 508 are rejected under 35 U.S.C. 102(e) as being anticipated by Barry *et al.* (Pat. 6,081,786).

Barry *et al.* disclose a system, method, and computer program product for the selection of treatments. Their system includes a model modifiable by the input of patient data (column 8, lines 5-20), listing treatment protocols (column 7, lines 1-22), and ranking the proposed treatments for the optimal treatment protocol base on various variables such as drug efficacy or cost (column 13, lines 27-30). Their invention can be embodied in a computer readable medium, computer program product, Internet and telephones (column 8, lines 57-67).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1631

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-3, 6-19, 22-28, 31-44, 45-52, 55-65, 234-235, 246-249, 260-263, 274-276, 279-294, 295-298, 301-314, 315-318, 321-327, 330-331, 466-467, 478-481, 494-495, and 506-509 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry *et al.* (Pat. 6,081,786) and in view of Fink *et al.* (Pat. 5,808,918).

Barry *et al.* disclose a method of recommending treatments for various disease such as cancer (column 6, line 53), however, they do not disclose predicting the progression of the disease or using a realistic biological model. They also disclose the use of artificial intelligence, which suggests the use of heuristics in their method (column 7, lines 45-49) Their method is designed for scientists and medical doctors (column 7, line 66- column 8, line 4).

Fink *et al.* disclosing using a realistic biological process model for drug treatment evaluation (see abstract). This model incorporates the effects of treatment on cell populations (column 11, line 41-45). The also analyzes pharmacokinetic,

Art Unit: 1631

pharmacodynamic, dosage, selecting the correct patient population for clinical trials, and patient characteristics (column 12, line 67-column 13, line 4; column 13, lines 26-34). This model can be modified to determine the length of time necessary for a treatment reach a desired disease stage such bacterial load (column 12, line 49-55). It incorporates other factors in the treatment of disease such as genetic and environmental factors, drug efficacy and side effects (column 3, lines 30-40). It allows the user to predict the outcome of treatments and the optimal time to take clinical measures (column 3, line 20-24; column 13, line 23-34). The use is able to alter the parameters and determine the means of manipulating the data in a meaningful way such as using a fitness function (column 5, line 56-column 6 line 3). Fink *et al.*'s method is designed for drug developers or scientists (column 13, lines 5-11).

Barry *et al.* mentions the use of their invention for various diseases, but does not disclose a specific method for cancer. Fink *et al.* discloses a method that is applicable to any cell population or any disease. Thus one would be motivated to incorporate Barry *et al.*'s teachings of recommending a treatment protocol with Fink *et al.*'s method of modeling. It would have been prima facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the two methods in order in increase the flexibility of Barry *et al.*

10. Claims 1-65, 234-331, and 466-509 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry *et al.* (Pat. 6,081,786) in view of Fink *et al.* (Pat. 5,808,918) and further in view of Thalhammer-Reyero (Pat. 5,930,154).

Barry *et al.* disclose a method of recommending treatments for various disease such as cancer. However, they do not disclose predicting the progression of the disease or using a realistic biological model.

Fink *et al.* disclose a method of modeling biological systems for drug development and the prediction of disease progression. However, they do not disclose using cell populations composed of bone marrow cells, heuristics, cell cycles, or the compartmentalization of cells.

Thalhammer-Reyero discloses a method for modeling biological systems organized in discrete compartments (see abstract). She teaches a model of the progression through different cell states in each compartment (column 34, lines 28-51). A compartment further encapsulates several compartments (column 24, lines 13-14). The number of cells in each compartment is determined by stepwise equations (column 32, lines 10-28). This model also determines the distribution of cell states such as G1, S, G2, M, and G0 (column 23, lines 20-50). Within each compartment, the stage of the cell, external environment, and the population of cells are factors used to determine the progression of a cell population (column 25, lines 18-36). Her method allows the modeling of homogenous cell populations including bone marrow cells such as neutrophils (fig.5, column 34, line 10-25). This method is embodied in a compute program product that utilizes mathematical modeling and heuristics (column 6, line 52-column 7, line 10).

Fink *et al.*'s invention is aimed to create a multi-variable and intergrated view of a biological system. Thalhammer-Reyero has created a system that allows the user to

Art Unit: 1631

have a high level of control over models at the subcellular level. Thus one would be motivated to combine Fink *et al.*'s invention with Thalhammer-Reyero's invention in order to create a more complete picture of a biological system. In addition, Thalhammer-Reyero discloses the use of heuristics, which allow the user to draw relationships between biological events that have not been clearly defined. This would be great benefit to Fink *et al.*'s method, since many biological processes are not clearly understood. However, both inventions are aimed primarily at research scientists or clinical scientists and not the practicing physician. In order to broaden the use of these inventions, one would be motivated to add Barry *et al.*'s invention, which is designed to accommodate practicing physicians. Thus, it would have been prima facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine these three inventions for enhanced functionality and utility.

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (703) 306-5439. The examiner can normally be reached on 7:30am-4:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

Application/Control Number: 09/691,053

Page 8

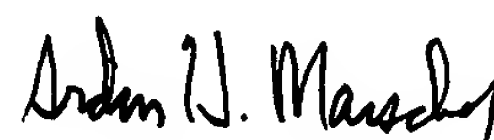
Art Unit: 1631

308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.



Jerry Lin
April 27, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER